

DRAFT
Department of Health Professions
Board of Health Professions
REGULATORY RESEARCH COMMITTEE
May 8, 2012

TIME AND PLACE: The meeting was called to order at 9:05 a.m. on Tuesday, May 8, 2012, Department of Health Professions, 9960 Mayland Drive, 2nd Floor, Board Room 2, Henrico, VA, 23233.

PRESIDING OFFICER: Jonathan Noble, OD

MEMBERS PRESENT: Jonathan Noble, OD
Yvonne Haynes
Allison Gregory

MEMBERS NOT PRESENT: Maureen Clancy
Charlotte Markva

STAFF PRESENT: Elizabeth A. Carter, Ph.D., Executive Director for the Board
Justin Crow, Research Assistant
Laura Jackson, Operations Manager

OTHERS PRESENT: Michael Brown
Michael Jurgensen, MSV
Scott Johnson, HDJN
Tyler Cox, HDJN
Don Harris, Inova Health System
Rick Shinn
Susan Ward, VHHA
David Fitzgerald, CCP President
Lee Bechtel

QUORUM: A quorum was established with 3 members in attendance.

AGENDA: No additions or changes were made to the agenda.

PUBLIC COMMENT: Dave Fitzgerald, Virginia Perfusion Society
Mike Brown, Board Member, Virginia Perfusion Society
Mr. Fitzgerald and Mr. Brown referred to the handout material that was provided the Regulatory Research Committee April 26, 2012. Mr. Fitzgerald stated that the Perfusionists represented by the VPS strongly believe that the highly technical nature of a Perfusionists scope of practice require licensed regulation in the state to help mitigate serious harm to surgical patients and preventing adverse patient events and medical mistakes due to human error is paramount. Licensing is the least restrictive method of regulation consistent with the need for protecting patients requiring cardiopulmonary bypass and related cardiovascular and cardiothoracic surgical procedures.
(Attachment 1)

APPROVAL OF MINUTES: On properly seconded motion by Ms. Haynes, the Committee approved the meeting minutes for February 14, 2012 as presented.

EMERGING Nothing to report at this time.

PROFESSIONS UPDATE:
EXECUTIVE DIRECTORS
REPORT: On properly seconded motion by Ms. Gregory, the committee made motion to approve the Perfusion Sunrise Review request. All members were in favor, none opposed. The Sunrise Review request will now be sent to the Full Board for review at the next meeting.

Dr. Carter reported the status of the Nurse Practitioner study. Handouts were provided as an overview of the study and Dr. Carter stated that the report submitted to the committee at the July 2011 meeting constitutes as the final report.

NEW BUSINESS: Dr. Carter advised the committee of the review being undertaken by the Department concerning the comparability of military credentialing with licensure requirements. This review is being undertaken in response to a request from Delegate Christopher P. Stolle, M.D. Dr. Carter also noted that this issue is a high priority across the country. A special federal joint task force has been formed comprised of representatives from the U.S. Departments of Defense, Veterans Affairs, Labor and Office of Personnel and Management, and from each of the branches of military service has been created to help address the issue. However, because professional licensure is obtained through the states, not the federal government, the Joint Task Force has requested assistance from five states: Washington State, Illinois, Maryland, Colorado, and Virginia to obtain insight into what is needed by states to determine licensure qualifications. Dr. Carter reported that she will be updating the Board on the review's progress.

The Board of Pharmacy has requested a study to be done on their scope of work. Attached is a workplan outlining the timeline for completion of this request. On properly seconded motion by Ms. Haynes, all members voted in favor of conducting the study and approved the workplan (Attachment 2)

ADJOURNMENT: With no other business to conduct, the meeting adjourned at 10:47 a.m.

Jonathan Noble, OD
Chair

Elizabeth A. Carter, Ph.D.
Executive Director for the Board



Virginia Perfusion Society
Inova Fairfax Hospital, Cardiovascular Perfusion
3300 Gallows Road, Falls Church, VA 22042

David Fitzgerald, CCP President
Richard Zacour, CCP Vice President
Mike Brown, CCP Board Member
Zack Beckman, CCP, Board Member

April 26, 2012

Laura L. Jackson
Operations Manager
Board of Health Professions
Virginia Department of Health Professions
9960 Mayland Drive, Suite #300
Henrico, VA 23233

Dear Ms. Jackson;

Enclosed are 18 informational packages, including the joint Statement of myself and Mr. David Fitzgerald, for the May 8th Research Committee and Board meeting.

Both Mike Brown and David Fitzgerald, along with Lee Bechtel, who is working with the Society on this matter will be in attendance. Only myself and David will be presenting to the Committee.

We appreciate the opportunity to present our views on the VPS application. Should things change with our schedules, we will advise. Otherwise, you can contact me or Lee Bechtel, at 301-801-8402 (mobil) or email at balobby@verizon.net.

Thanks for your assistance.

Sincerely,

Mike Brown, CCP
Perfusion
Cardiovascular and Thoracic Surgery
Mary Washington Hospital
540 - 741-6351 (mobil)
540 - 372-7132 (pager)



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Inova Fairfax Hospital, Cardiovascular Perfusion
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**STATEMENT OF DAVID FITZGERALD, CCP PRESIDENT
AND MIKE BROWN, CCP, BOARD MEMBER, VIRGINIA PERFUSION SOCIETY
TO THE
VIRGINIA BOARD OF HEALTH PROFESSIONS**

MAY 8, 2012

I am David Fitzgerald and currently serve as the President of the Virginia Perfusion Society (VPS). I also currently serve as the President of the national professional association for perfusionists, the American Society of Extracorporeal Technology (AmSECT). I am the Chief of Cardiovascular Perfusion for Cardiac, Vascular and Thoracic Surgical Associates, PC, serving surgical patients in the D.C. Metropolitan region, including INOVA Fairfax Hospital, Falls Church, VA.

I am Mike Brown, a VPS Board Member and the Chief of Perfusion, Cardiovascular and Thoracic Surgery, Virginia Heart & Vascular Institute, Mary Washington Hospital, Fredericksburg, VA. Both of our employers participate in the Virginia Cardiac Surgery Quality Initiative (VSCQI). This is a Consortium of 16 hospitals and 10 cardiac surgical programs at the 21 hospitals that provide open-heart surgery services in the Commonwealth. The Consortium collects data on the delivery of cardiovascular and cardiothoracic cases done on adults in the Commonwealth.

We appreciate the opportunity to appear today on behalf of the Society's Sunrise Proposal/Application which the board received on January 17, 2012. We are aware of the board's February 14th meeting and the research committee decision to table consideration of the application until the level of "urgency" could be ascertained. We are aware of the workload before the research committee. We hope that our comments will assist with the decision to move forward. We believe that moving forward on the study phase of the process should be considered sooner rather than later, but are pleased that the process is actively underway.

THE PROFESSION AND THE VPS

Between 2003 and 2010, more than 48,000 residents in our state received open-heart surgery, ranging from coronary artery bypass procedures to heart and lung transplantation. Each year, approximately 7,000 Virginians of all ages, including children under the age of 18 years of age, require the services of a perfusionist. We have provided a brochure with descriptions and illustrations of the perfusion profession, our professional education and training, and the critical care services the 90 perfusionists in the state deliver each day in the 21 open-heart surgical programs in the Commonwealth.

Our application includes both quantitative and qualitative evidence-based information to assist in the study phases of the credentialing recommendation process of the board. The society welcomes the opportunity to provide any additional information needed by members or staff.

The VPS has been in existence for several years and until recently focused only on informing and educating our colleagues on new surgical procedures and devices in the safe delivery of care to thousands of Virginians. For example, this is the fourth year the Society has cosponsored the Mid-Atlantic VAD and ECMO Symposium with both the Maryland and District of Columbia Perfusion Societies. Only recently have our members and the VPS leadership actively engaged the desire for state legal credentialing of our profession. Our national professional society, headquartered on the other side of Richmond, has had a Government Relations Program dedicated to state legal credentialing for 17 years. During this time, 18 states have enacted legal credentialing for perfusionists. Fifty-four (54%) percent of perfusionists in the United States are recognized as licensed professionals. A list of these states is in the brochure, as well as a list of disciplinary actions taken in licensed states. The states of Kansas and New York, and the District of Columbia have pending legislation to license perfusionists. The most recent state to legally recognize our profession is Maryland, in 2011.

It has taken time to arrive to this stage, as Virginia perfusionists have carefully vetted the merits and public benefits to perfusion licensure. As a result of our investigation, the perfusionists represented by the VPS strongly believe that the highly-technical nature of a perfusionist's scope of practice require licensed regulation in the state to help mitigate serious harm to surgical patients. Virginia perfusionists, for the most part, have accepted the responsibility of being held accountable for their actions and the need for required state minimum entry to practice standards for our profession. The personal cost of licensing perfusionists is minimal compared to the hospital costs for Medicare and the state Medicaid insurance program that are associated with perfusionist medical errors and patient safety. More importantly, preventing adverse patient events and medical mistakes due to human error is paramount for VPS members. Licensing is the least restrictive method of regulation consistent with the need for protecting patients requiring cardiopulmonary bypass and related cardiovascular and cardiothoracic surgical procedures. Related to this reality is the ongoing and future evolution with cardiovascular and cardiothoracic devices and surgical techniques employed, both inside and outside of the operating room, that encompass the specialized education, training and skills of a perfusionist.

URGENCY OF VPS APPLICATION

We believe the following should be taken into advisement when considering moving forward with the VPS Application.

The Research Committee recently decided that licensure is appropriate for Laboratory Scientists and Medical Laboratory Technicians. A potential future problem may occur for perfusionists and hospitals with the performance of "Point-of-Care" testing in the operating room. Depending upon the defined scope of practice and categories of testing that are written into statutory law, there could be complications with perfusionists and their performance of critical Activated Clotting Time (ACT) testing

and blood gas testing during open-heart surgical procedures. This issue has arisen in other non-licensed perfusionist states that have licensed Medical Laboratory Technicians. This happens to be a current legislative issue in the states of Alaska, Minnesota, and South Carolina.

There may also be an existing incongruity with state law with non-licensed perfusionists in the clinical performance of cases involving Extra-Corporal Membrane Oxygenation (ECMO) with licensed respiratory therapists. When ECMO is employed, the patient requires long-term cardio-pulmonary support via a modified heart-lung machine. Once an ECMO pump is placed by a perfusionist in consultation with a surgeon, the patient is transferred to the Intensive Care Unit (ICU) and the perfusionist continuously adjusts and optimizes ECMO pump settings to ensure safe recovery and delivery of critical care. ECMO procedures are universally performed in a multi-disciplinary collaborative with physicians, respiratory therapists, and critical care nurses - all of whom are responsible for different facets of the patient's care strategy. ECMO is a versatile and life-saving technology often reserved for the most critically-ill patients in the hospital. ECMO is typically considered when the expected mortality of a patient reaches 80%. The most common uses of ECMO therapy range from pre-surgical implantation as an adjunct to acute cardiogenic shock and cardiac arrest, to recovery from invasive surgical procedures such as heart and lung transplantation. ECMO therapy is a standard of care for all hospitals performing neonatal and pediatric cardiac congenital surgery. Congenital heart abnormalities are the most common type of birth defect, occurring in 1 out of every 120 live births.

The question with ECMO is whether unlicensed perfusionists are engaged in licensed medical functions without recognized state authority to do so? Respiratory therapists are licensed and regulated by the Board of Medicine (§54.1-2900 et seq. of the Code of Virginia). The medical scope of practice statutory and administrative regulations for licensed Respiratory Therapist's, in part, states the following:

"Part IV. Scope of Practice

Practice as a licensed respiratory care practitioner means, upon receipt of written or verbal orders from a qualified practitioner and under qualified medical direction, the evaluation, care and treatment of patients with deficiencies and abnormalities associated with the cardiopulmonary system. This practice shall include... the administration of medical gases exclusive of general anesthesia; The practice of respiratory care shall include such functions shared with other licensed health professionals as cardiopulmonary resuscitation;... and invasive and noninvasive advanced cardiopulmonary monitoring."

In the September 25, 1995 published board report recommending the need to license respiratory therapists, the overlapping clinical tasks of perfusionists and respiratory therapists are noted. Respiratory care therapists "treat patients with difficulties due to various health problems including those involving cardiopulmonary complications, or post-surgical complications" (Pg. 3).

What HAS changed since 1995 is the complexity of the devices employed with patients needing ECMO, and newer generation mechanical circulatory support devices being used in hospitals. Respiratory therapists are not trained or tested with the construction and operation of modified heart-lung machines. Anyone clinician providing ECMO support without successfully graduating from an

outcomes, surgical infections, and the human and financial costs associated with traditional managerial approaches. While FOCUS is laudable in purpose, Virginia perfusionists start from behind the professional learning curve. For example, there exists no motivation to stay abreast with changes in clinical best practices in states with without a requirement for continuing medical education. Additionally, there is no state peer review mechanism for actions involving a perfusionist that may result in patient harm.

NEW SURGICAL DEVICES AND TECHNIQUES

Cardiovascular and cardiothoracic surgical techniques and devices are constantly evolving inside and outside of the operating room. Included in the brochure is a recent position statement of our national professional society (AmSECT) on portable Extracorporeal Cardiopulmonary Life Support (ECLS) devices, which are gaining the attention of hospital emergency room administrators. These devices benefit patients suffering from acute respiratory failure or acute myocardial infarction. As perfusionists, we know the benefits and limitations of these devices, which we operate routinely to rescue patients with profound shock.

Device manufacturers have realized the market for these advanced devices and are bringing Mechanical Circulatory Support (MCS) to the doorsteps of hospitals across the country. There is a risk that these devices may not include the unlicensed perfusionists in Virginia, even though they are the best-educated and trained non-physician allied health professional to safely operate them. It is important that the operators of these devices have the background and necessary clinical skill sets to safely manage how they are used on patients. The absence of recognized state credentialing and medical scope of perfusionist practice is a critical barrier in this regard.

The use of portable Ventricular Assist Devices (VADS) is also in the realm of current and future of cardiovascular devices directly involving perfusionists. VADs are surgically implanted mechanical pumps used to increase cardiac output. When a VAD is surgically inserted, the perfusionist is the person who prepares the device for the surgical field, in close collaboration with the cardiovascular surgeon. Post-operatively, they are the expert technical resource for the device. ICU physicians and nurses direct most troubleshooting and technical issues to the perfusionist when problems persist during the post-operative recovery period. The Joint Commission (TJC), formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits and certifies hospital VAD programs. INOVA Heart and Vascular Institute, in Falls Church, is one such facility. The Joint Commission accredits over 19,000 health care organizations and programs in the United States. The majority of states recognize Joint Commission accreditation as a condition of hospital licensure and the receipt of federal Medicare and state Medicaid reimbursement.

The Joint Commission accreditation standard for the allied health professions involved with VADs is licensing, which perfusionists are not in the Commonwealth. It is not clear when this window will close, which may well effect hospital VAD certification and the ability of hospitals to make this device available to the citizens in their respective communities that are candidates.

accredited perfusion-training program has not received formal training. Perfusionists cannot be licensed as respiratory therapists. If both professions are licensed this issue would be resolved not only for perfusionists but for hospital surgical department managers and hospital risk managers.

There is the administration of medications, blood products, and narcotics to persons by an unlicensed non-physician medical staff person. In the course of open-heart surgical cases, perfusionists administer blood, drugs, and anesthetic agents via the heart-lung machine, under the direction but not constant supervision of a surgeon or anesthesiologist. This only occurs in the operating room. This is generally reserved only for licensed professions. In short, this creates a large degree of ambiguity with respect to an existing patient safety double standard for perfusionists in performing these medical tasks.

Depending on hospital protocol, an anesthesiologist prescribes appropriate medications and amounts to be administered but does not supervise patient delivery in the operating room. The physiological parameters read from the heart-lung machine and blood gas measurements taken directly from the patient, help determine the adequacy of patient care. A perfusionist exercises a great degree of independent medical judgment when making these decisions. The competency of the perfusionist allows the cardiovascular surgeon to maintain their focus on the surgical field and the corrective procedure. There is a continuous dialogue that takes place between the surgeon and the perfusionist. Through effective communication the cardiac surgical team can minimize iatrogenic harm to the patient while the surgeon concentrates on the surgical correction. The surgeon is not in a position to closely monitor critical care parameters such as blood pressure, blood flow, electrolytes, and oxygen levels. A surgeon must rely on the perfusionist to monitor and maintain a patient's physiology and on the perfusionist's judgment to intervene when conditions are outside of the standard operating procedure. The document "Examples of Perfusionist Decision Making" in our brochure helps explain this in a comparative medical treatment scenario.

Operating a heart-lung-blood machine carries significant risk for irreversible patient injury, which can result in death. The federal Food and Drug Administration (FDA) classifies the medical devices used by perfusionists as having Levels 2 and 3 risks of patient harm. These are the highest classifications for medical devices assigned by the FDA.

Reliable State and national statistical evidence supports the potential for 50 to 60 serious long-term adverse medical outcomes attributable to heart-lung machine device malfunctions. There is the potential for 5 to 6 persons each year suffering a death attributable to the incompetent delivery of perfusion services – human or mechanical - in the Commonwealth each year. These are estimates based on national surveys and using Virginia Cardiac Surgery Quality Initiative (VSCQI) data for cases performed only on adults in the Commonwealth at the participating Consortium hospitals.

Included in our brochure is "Better Teams, Safer Patients", a collaborative of cardiac surgery professional groups that includes perfusionists and a VPS representative. The motivation was to identify and address barriers to reducing human errors in the operating room. This collaborative effort focuses on human dynamics and hospital cultures that obstruct best practices to reduce adverse patient medical

outcomes, surgical infections, and the human and financial costs associated with traditional managerial approaches. While FOCUS is laudable in purpose, Virginia perfusionists start from behind the professional learning curve. For example, there exists no motivation to stay abreast with changes in clinical best practices in states with without a requirement for continuing medical education. Additionally, there is no state peer review mechanism for actions involving a perfusionist that may result in patient harm.

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STANDARDS FOR PERFUSIONIST PRACTICE

There are no general competencies or mandated standards for the entry to practice our profession in the Commonwealth. The American Board of Cardiovascular Perfusion (ABCP) only voluntarily certifies Virginia perfusionists. After graduating from a CAAHEP (Commission on Accreditation of Allied Health Education Programs) accredited training program, a perfusionist becomes "board eligible" to register for the ABCP board examination. Perfusionists can fail the examination continually but remain "board eligible". There is no limit on the number of times the certification examination can be taken.

Many open-heart hospitals in the Commonwealth, but perhaps not all, require the successful completion of the board examination as a precursor for employment. There is no state requirement we are aware of that prohibits a hospital from hiring a "board eligible" perfusionist. Moreover, there may not be the requirement that certification be maintained.

Voluntary certification requires the demonstration of having completed 45 hours of continued medical education units every three years. A certified perfusionist can allow their certification to lapse and avoid any requirement to demonstrate professional activity. The ABCP possesses neither a peer review committee nor disciplinary board within the organization when it comes to maintaining its recertification process. There is no mechanism to revoke certification status in cases of unsafe or negligent care to patients.

Perfusionists must be competent in the administration of care to prevent patient injury. There is a high amount of risk involved due to the use complex mechanical devices and invasive surgical procedures that require extensive training and demonstrated proficiency. For these and other reasons, we believe that licensure provides the least restrictive regulation required for public protection.

WHAT PERFUSIONISTS ARE NOT SEEKING WITH LICENSING

Regardless of being a licensed profession or not, perfusionists are not recognized providers eligible to bill the Medicare program for their services. It is established that private insurance companies adopt Medicare payment policies pertaining to who can bill for a medical service. Only recognized Medicare medical professions may bill under Part B of the Medicare program. Perfusionists are not on this list of recognized professions. Most perfusionists in Virginia are employed by hospitals; some are employed by physician surgical groups that bill Medicare for patient procedures. Three of the 21 hospitals with open-heart programs contract with a national perfusion service contract company, and these hospitals pay these companies for the services provided by their employed perfusionists.

Regardless of employment arrangement, on average, an experienced perfusionist's salary is between \$90,000 and \$101,000 thousand dollars per year. The starting salary for a perfusionist, on a national basis, is in the range of \$50,000-\$70,000 dollars. Licensure would have no demonstrative impact on the salaries and/or income levels of Virginia perfusionists based on survey data from AmSECT and other third parties.

The usual marketplace supply and demand principles associated with licensure - an increase in salary due to a reduced supply does not fit for the practice of perfusion. There are limited positions available at the 21 hospitals with open-heart programs in the state with an adequate supply of perfusionists nationally to fill vacancies or expanded program positions due to increases in caseloads. There are no other practice settings in which perfusionists can work, or be excluded from working. Information is contained in our Sunrise Application.

We are willing to answer any questions a board member or staff may have, now or in further follow-up written responses, in hard copy or digital formats.



Virginia Perfusion Society
Inova Fairfax Hospital, Cardiovascular Perfusion
3300 Gallows Road, Falls Church, VA 22042



David Fitzgerald, CCP President
Richard Zacour, CCP Vice President
Mike Brown, CCP Board Member
Zack Beckman, CCP, Board Member

Perfusionists are allied health care professionals who are responsible for operating the heart-lung machine during open-heart surgical procedures, such as Coronary Artery Bypass Grafting (CABG), valve repair/replacement, organ transplants, and other major cardiovascular or thoracic procedures. Additionally Perfusionists perform many additional tasks including autologous blood salvage, chemotherapeutic interventions and hemofiltration. Perfusionists perform highly specialized tasks in order to support their patient while they are on the heart-lung machine, including the administration of drugs, blood, and anesthetic medications to maintain a patient's natural physiologic state.

There are 90 perfusionists working at 21 hospitals with open-heart programs, including the VA hospital in Richmond. Sixteen of these participate in the Virginia Cardiac Surgery Quality Initiative (VSCQI). Several use a national perfusion service contact company to staff their departments. Based on VSCQI reporting data, every year at least 6,000 to 7,000 adults and children undergo an open-heart or another major cardiovascular surgical procedure. All of these procedures must involve a Perfusionist. Likewise, Perfusionists care for patients who require other types of support such as Extracorporeal Membrane Oxygenation (ECMO), Cardiopulmonary Support (CPS) and Ventricular Assist Devices (VAD) to name a few.

Perfusionists when operating these machines, often times independent of physician consultation, make decisions. Before an open-heart surgical case, an anesthesiologist will provide and recommend the anesthetic agents to be administered by the perfusionist via the heart-lung machine. During a surgical procedure the surgeon gives general direction to a perfusionist based on what the surgeon is trying to accomplish while he/she is concentrating on their portion of the case inside a patient's body. The perfusionist will, as needed administer drugs, blood and anesthetic agents while keeping the surgeon informed.

The surgeon is not continually monitoring patient blood pressure, blood flow, electrolytes, or oxygen levels. A surgeon does not directly supervise what the perfusionist is doing behind the heart-lung machine to maintain a person's physiology during a case. Surgeons rely on the perfusionist's independent medical judgments to maintain the well being of their patient and correct items that are out of normal limits. Perfusionists make corrections when something is wrong with the extracorporeal circuit maintaining a person's life. These decisions can include giving the patient more heparin, based on lab results, transfusing the patient due to a hematocrit that is dangerously low, adjusting the flow of oxygen to the patient, interpreting blood gases and making corrections as needed (i.e. giving sodium bicarb or calcium), and treating the patient with vasoactive medication, to manage the patient's blood pressure while on Cardiopulmonary Bypass (CPB).

At times a patient is unable to wean from bypass, for any number of reasons, and ancillary devices are placed to aid in the recovery process. These devices may include a Ventricular Assist Device (VAD) or Extracorporeal Membrane Oxygenation (ECMO) devices. When a VAD is placed, the perfusionist is the person who prepares the device for the surgical field. Post-operatively, they are the "point person" for this device. If the ICU nurses have questions or problems, the Perfusionist is called to go to the ICU to troubleshoot the device. When ECMO is used the patient either has a very sick heart or a pulmonary issue that requires long term support via a modified heart-lung machine. Once ECMO is placed, the patient is transferred to the ICU and a Perfusionist sits with the patient giving medications and maintaining the integrity of the ECMO device.

At open-heart hospitals with ECMO programs, cases are usually staffed by perfusionists and licensed respiratory therapists. Cardiopulmonary Support (CPS) is another modified heart-lung machine that may be utilized in emergent situations. Often times it is reserved for the patients that arrive at the hospitals via the Emergency Department to go to the Cardiac Cath Lab in cardiogenic shock or full cardiac arrest. Here, the perfusionist primes the device and the cardiologist places cannulae in the femoral artery and vein. The Perfusionist manages the patient much like ECMO or CPB cases.

Licensure is becoming the standard for the profession. ***Perfusionists are currently licensed in 18 states.*** The primary reason is to ensure patient safety and hold those who practice within the profession accountable. Since 1981 the American Board of Cardiovascular Perfusion (ABCP) has provided a national certification process. It is important to note that this certification is voluntary to both obtain and maintain. There are no mandated state requirements for its retention in states without licensure. If a perfusionist in Virginia chose not to obtain or maintain certification there are no prohibitions, although some hospitals require continued certification as a condition of employment. Otherwise, a perfusionist can practice without any oversight as to competency or continuing medical education. The ABCP does not have peer review or a disciplinary board within the organization. Therefore, there is no mechanism to remove a perfusionist's certification if they were to act improperly or to be negligent in providing patient care.

The federal Food and Drug Administration classifies the medical devices used by perfusionists as having Levels 2 and 3 risks of direct patient harm. These are the highest classifications for medical devices.

Perfusionist Licensing in Virginia

Virginia perfusionists are seeking licensure to ensure public safety and not as a means to improve professional compensation. Perfusionists cannot refer patients. Perfusionists are employed by hospitals, contracted for services by hospitals, or employed by surgical group practices. Payment for service is an implicit agreement between the provider of perfusion services and the hospital.

commercial insurance of an employer, or publicly funded insurance coverage by Medicare, Medicaid, or Worker's Compensation. Insurance payments are made to the hospital, or to a physician surgical group, and not directly to a perfusionist. Peer reviewed third party studies have shown that the future available supply of perfusionists in the currently licensed 18 states has not been materially impacted with licensing of the profession. Licensure would have no demonstrative impact on the salaries incomes levels of Virginia perfusionists. A 2011 University of South Carolina national perfusion salary survey (695 Responses) found an average salary of \$109,000 with 13 years of experience.

Perfusion Education & Training

Currently there are 19 perfusion education programs in the United States accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). None are located in Virginia. Upon completion of clinical and didactic course work the graduate will have a minimum of a certificate of completion or a baccalaureate degree. Several programs offer a masters degree. Formal training and successful completion of an accredited program is required for all persons wishing to sit for the certification examinations.

In general, the prerequisite science courses needed for entrance into an education program include, but are not limited to anatomy, physiology, math, statistics, chemistry, physics, and biology. The courses required for the completion of perfusion education include further study in the science courses with emphasis on their relationship to cardiovascular systems, perfusion techniques, devices, pharmacology, cardiac pathology, biostatistics, and a research project. The clinical practicum portion involves exposure to the various aspects of the scope of the practice including all age groups of patients, including pediatric and neonate persons born with congenital heart defects.

Virginia Open Heart Hospitals

Sentara Norfolk General	Norfolk
CJW Medical Center	Richmond
Bon Secours Regional Center	Mechanicsville
VC University Health System	Richmond
Inova Alexandria Hospital	Alexandria
Bon Secours Saint Marys	Richmond
Riverside Regional	Newport News
Henrico Doctors'	Richmond
Sentara Virginia Beach	Virginia Beach
Virginia Hospital Center	Arlington
Lewis - Gale Medical Center	Salem
Lynchburg General Hospital	Lynchburg
Inova Fairfax Hospital	Falls Church
University of Virginia	Charlottesville
Bon Secours – Maryview	Portsmouth
Winchester Medical Center	Winchester
Mary Washington	Fredericksburg
Carilion Roanoke Memorial	Roanoke
Danville Regional Medical	Danville
Veterans Administration	Richmond
Children's King's Daughters	Norfolk

Perfusionist Credentialing

The American Board of Cardiovascular Perfusion (ABCP) with successful passage of a two-part examination certifies perfusionists. Certification is voluntary to achieve and voluntary to maintain. A perfusionist must graduate from an accredited training program to take the examination. The examination can be taken without passage as many times as they may wish. Meanwhile, they are "board eligible" and can remain "board eligible" and employed in states that do not license the profession. A few hospitals in Virginia have continued certification as a condition of continued employment. The lack of adequate hospital "credentialing" to assure continued professional competency does exist in the State. As an unregulated profession, the only institutional mechanism to protect the public from unqualified perfusionists is the Joint Commission on Accredited Health Organization (JCAHO) requirement that hospitals "credential" health care workers and physicians. Hospital credentialing is done through a random inspection process. The administration of a hospital has a profession, perfusionists, that comprise very few workers whose medical scope of practice is not legally defined. It is not known how actively Virginia hospitals enforce these professional qualifications as a component of their institutional standards of care.

Statistical Estimate of Perfusionist Related Surgical Case Injury or Deaths

2006 Cases	Perfusionist Caused # of Injuries/Death	2007 Cases	Perfusionist Caused # of Injuries/Death	2008 Cases	Perfusionist Caused # of Injuries/Death	2009 Cases	Perfusionist Caused # of Injuries/Death	2010 Cases	Perfusionist Caused # of Injuries/Death
6,025	6 Persons	5,940	6 Persons	5,436	5 Persons	5,435	5 Persons	5,227	5 Persons
Data Sources – VSCQI Virginia Cardiac Surgery Quality Initiative - Consortium of 16 hospitals and 10 cardiac surgical practices providing open-heart surgery in the Commonwealth of Virginia. Includes Coronary Artery Bypass Only, MV Replacement + CAB, AV Replacement + CAB, MV Replacement Only, MV Repair, AV Replacement, AV Replacement + MV Replacement, MV Repair + CAB). OPTN – Organ Procurement Transplant Network. US Department of Health and Human Services, Health Resources and Services Administration, heart, heart/lung transplants in Virginia. Reed and Stafford, in the book, Cardiopulmonary Bypass, second edition, have reported that the number of injuries or deaths from accidents of a perfusionist was/is 1 per 1,000 surgical cases.									

Examples of Perfusionist Decision Making

A. Compare the path of a blood gas [or ACT] taken during cardiopulmonary bypass in the Operating Room (On Pump) with one take in the Intensive Care Unit (ICU) post-operatively:

1. Sample taken
 - In the ICU: This requires a Doctor's Order – written, verbal (with verification).
 - On pump: The perfusionist decides based on time interval or events during the case.
2. Sample analyzed
 - In the ICU: This could be point-of-care testing by the RN or sent to the lab.
 - On pump: The perfusionist operates the analyzer.
3. Sample results
 - In the ICU: This would be resulted via the point-of-care analyzer or be reported to the RN from the lab.
 - On pump: The perfusionist gets the results from the analyzer.
4. Interpretation and intervention
 - In the ICU, the RN (licensed):
 - a. Must report the result to the MD.
 - b. The MD interprets the result.
 - c. The MD gives the RN an order (written or verbal with verification) to change the ventilation settings, i.e. decrease the FiO_2 to 40% [or give 3000 units of Heparin].
 - d. The RN then shares the order with the respiratory therapist (also licensed) who changes the ventilator setting [or RN administers Heparin].
 - On pump, the perfusionist (currently unlicensed):
 - a. Reads the result from the analyzer.
 - b. Interprets the result.
 - c. Makes an independent decision to decrease the FiO_2 [or the amount of Heparin to administer].
 - d. Changes the blender setting [administers Heparin].

B. Compare series of events to increase the patient's mean arterial pressure.

The patient's MAP is 78 mmHg.

- In the ICU:
 - a. The RN must report this to the MD.

- b. The MD decides to give the RN an order (written or verbal with verification) to give 100 mcg of phenylephrine and repeat PRN to increase the MAP to 100 mmHg.
 - c. RN follows the order, administers 100 mcg of phenylephrine.
- On pump:
 - a. The perfusionist decides independently how much phenylephrine to administer (and how often) to get to the target MAP of 100 mmHg.

C. Compare the events to increase the patient's cardiac index:

The patient's cardiac index is 1.8 L/min/ m²; MAP 62 mmHg; SVR 1200 dynes-sec/ cm⁵; urine output 30 mL/hr.

- In the ICU:
 - a. The RN reports the patient condition to the MD.
 - b. The physician interprets information
 - c. The physician orders (verbal or written with verification) RN to:
 1. Inject 500 mL 5% Albumin IV – to increase blood volume.
 2. Start Dopamine 5 mcg/ kg/ min to increase cardiac output and therefore increase MAP.
 - d. Report condition to MD in 30 minutes.
- On pump, the perfusionist interprets the same information and independently decides to:
 - a. Add 300 mL Plasmalyte A to increase the reservoir volume and
 - b. Increase the RPMs of the arterial pump to increase cardiac output.
 - c. Give 100 mcg phenylephrine to increase MAP to target
 - d. Continuously monitors patient condition and acts independently to maintain homeostasis.

D. Compare the expectations of the surgeon regarding patient status:

- In the ICU:

Licensed personnel (RN) caring for the patient post-operatively are expected to keep the surgeon informed of changes to the patient's status so surgeon can interpret information and give the orders to be carried out in the care of the patient. RN may not employ independent decision making other than to act within very specific protocols (standing orders) approved by surgeon.

- On pump:

The perfusionist is expected to care for the patient while the surgeon concentrates on the operation. Target parameters for MAP, temperature, amounts of cardioplegia delivered are specific to the surgeon preference. Achieving target parameter is left to the perfusionist. The timing and frequency of the lab testing, interpretation, and intervention is left to the perfusionist to independently consider.



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Family Sues Um Medical Center In Death

July 30, 2009 | By Liz F. Kay | Liz F. Kay.liz.kay@baltisun.com

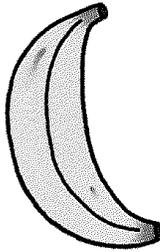
The family of a Westminster man who died after lung transplant surgery last year has filed a wrongful-death suit against the University of Maryland Medical Center and a subcontractor for what they say was a botched procedure.

According to the lawsuit, the family of Bryan Harris alleges that a contracted staffer incorrectly removed a clamp after the surgery in June 2008, allowing all of the patient's blood to drain into a bucket.

Harris, 51, is survived by his wife, his parents and two children. "They're devastated by the loss of a loved family member who should not have died," said their attorney, Michael Warshaw of Baltimore.

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The staffer is not named in the suit because it's not clear who was at fault, the attorney said. Two employees, known as perfusionists, were working during the surgery, and another came to relieve them after the procedure.

Warshaw said the family was initially told that Harris died of natural causes. However, the surgeon's report indicated that the clamp had been removed after the surgery. The suit alleges that the hospital also reported to the state medical examiner's office that the cause of death as "multiple system organ failure."

"Not only had [Harris' wife] not been told, but the medical examiner's office was not provided the information about what was the true cause of death," Warshaw said.

The medical examiner later altered the death certificate to list the cause of death as acute blood loss.

The perfusionists worked for the Coalition of Perfusion Services Inc. The company could not be reached for comment.

In a statement, representatives of the University of Maryland Medical Center said: "We have been aware of this matter since the time of the sad and unfortunate event. Since that time, we have had ongoing conversations with the Harris family and their attorneys. We are disappointed that suit has now been filed in light of our efforts toward an amiable resolution."

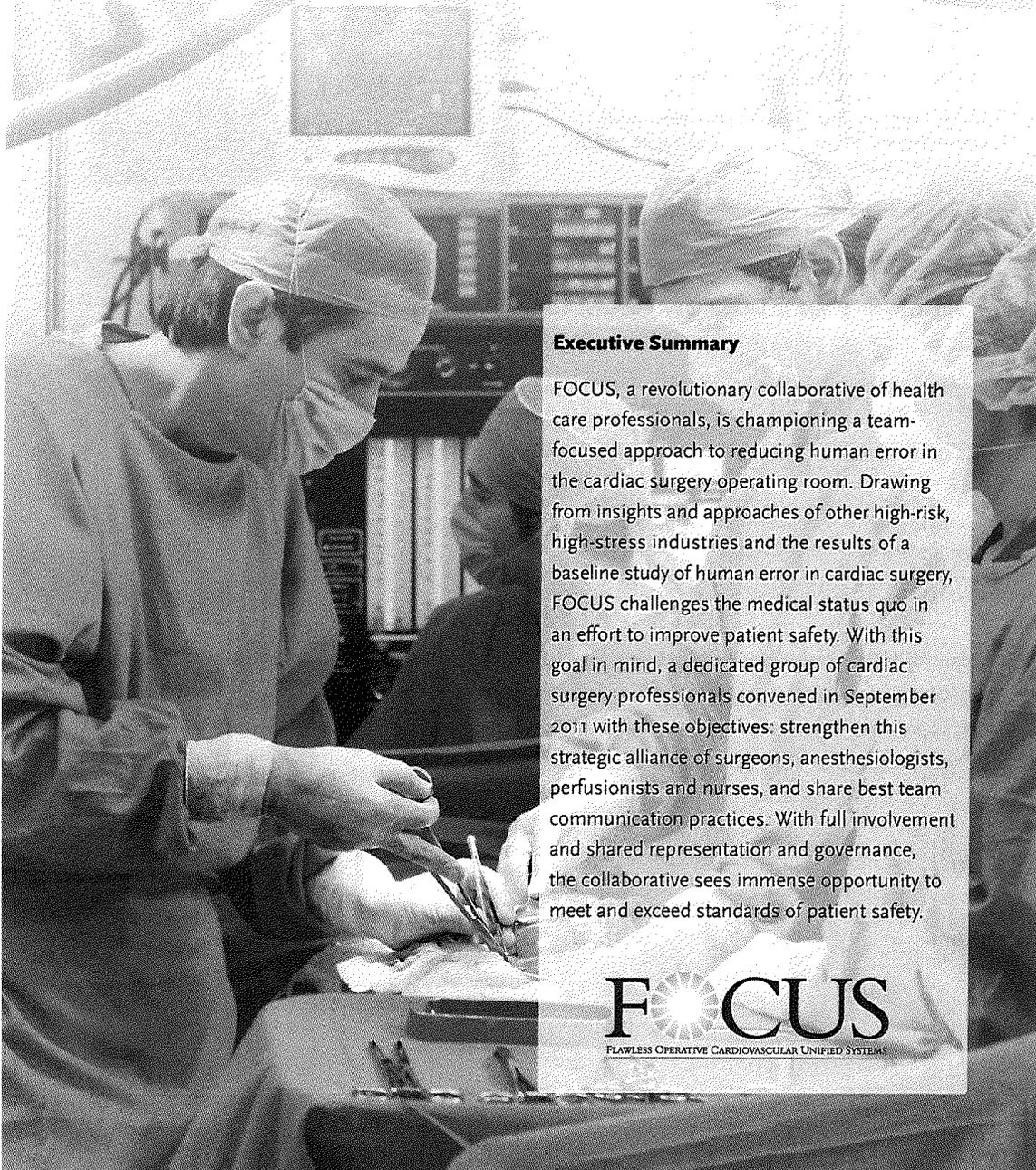
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Better Teams, Safer Patients

Cardiac Surgery Professionals Collaborate to Reduce Human Error



Executive Summary

FOCUS, a revolutionary collaborative of health care professionals, is championing a team-focused approach to reducing human error in the cardiac surgery operating room. Drawing from insights and approaches of other high-risk, high-stress industries and the results of a baseline study of human error in cardiac surgery, FOCUS challenges the medical status quo in an effort to improve patient safety. With this goal in mind, a dedicated group of cardiac surgery professionals convened in September 2011 with these objectives: strengthen this strategic alliance of surgeons, anesthesiologists, perfusionists and nurses, and share best team communication practices. With full involvement and shared representation and governance, the collaborative sees immense opportunity to meet and exceed standards of patient safety.

F  **CUS**
FLAWLESS OPERATIVE CARDIOVASCULAR UNIFIED SYSTEMS

In 1999, the Institute for Medicine estimated 48,000 to 98,000 lives are lost each year in U.S. hospitals because of medical mistakes.¹ This is comparable to a fully loaded Boeing 737 crashing every day for a year. And this estimate is likely quite low, especially given the fact that the Centers for Disease Control and Prevention noted that over 2 million hospital-acquired infections occur per year, leading to more than 90,000 deaths annually.²

Of the roughly 357-500,000 patients who undergo cardiac surgery each year, 28,000 will have an adverse event, many due to human error.³

Between a quarter to one half of surgery complications involve human error.⁴



But it doesn't have to be this way. The vast majority of these complications are preventable.

Seventy-four Veterans Affairs hospitals recently reported an 18% reduction in their annual mortality rate. They achieved this reduction by teaching teamwork and changing the basic culture of the operating rooms.⁵

A recent study showed that certain surgical teamwork behaviors can save lives.⁶

Using a model of operational excellence based on the Toyota production model, a cardiac surgery program in Pennsylvania was able to achieve an operative mortality rate 61% lower than that expected in their region. The same surgery program's risk-adjusted rate of major complications was 57% lower.⁷

How were such impressive life-saving results realized when so many patient injuries are reported? By taking a team-focused approach to reducing human error in the cardiac surgery operating room—an approach that is at the center of a revolutionary collaborative called FOCUS, which stands for Flawless Operative Cardiovascular Unified Systems.



Increasing patient safety and improving patient outcomes by reducing human error in cardiac surgery

Setting New Precedents with FOCUS – Boston, 2011



These are precisely the historical precedents that a group of determined cardiac surgeons, anesthesiologists, perfusionists and nurses gathered in Boston to discuss. Their goal: to identify a

“The healthcare injury rate is 30 times higher than that of any other major industry!” —surgeon

national collaboration to challenge these precedents, and develop a five-year strategic plan to realize significant, dramatic improvements in patient safety and outcomes by reducing human error.

The idea for FOCUS had its genesis in 2001, when Dr. Bruce Spiess, a Virginia Commonwealth University School of Medicine cardiac anesthesiologist with a passion for reducing errors, asked the Society of Cardiovascular Anesthesiologists (SCA) to underwrite the initial stages of a national effort to improve patient safety and reduce human error. The SCA established a separate

“We need to document and analyze near misses.” —anesthesiologist

foundation—the Society of Cardiovascular Anesthesiologists Foundation (SCAF)—to oversee and fund this work. To acquire baseline data, the SCAF, in collaboration with the Johns Hopkins University Quality and Safety Research Group (QSRG), conducted an observational research project—Locating Errors through Networked Surveillance, commonly referred to as LENS. Conducted

from 2008 to 2010, LENS studied the causes of human error in cardiac surgery in order to identify how those causes could be reduced or eliminated.

“Each one of us believes that we are ‘better than average,’ but we all can’t be.” —anesthesiologist

The study pointed repeatedly to the need to challenge Precedent #1 by focusing on teams rather than individuals. Why? Because most errors noted were “teamwork errors,” and the solutions to those errors are “teamwork solutions.”

For example, trained teams of observers sat in on 40 independent coronary artery bypass graft surgeries. The teams documented thousands of observations, including desirable behaviors, as well as those considered hazardous. Researchers then grouped these observations into 847 similar situations, which were then further grouped into the following 11 categories:

1. Care transition
2. Culture
3. Equipment
4. Infection prevention
5. Infusion pumps/drug errors
6. Knowledge/supervision
7. Operating room design
8. Preparation/planning
9. Situational awareness
10. Standardization
11. Teamwork communication

The study also made clear that overcoming Precedent #2 and affecting systemic change would require a national collaboration between the major societies whose members deliver patient care in the cardiac operating rooms.

With this goal in mind, a group of 17 cardiac surgeons, anesthesiologists, perfusionists and nurses gathered in Boston for a daylong symposium facilitated by Christine Cole, Kennedy School of Business, Harvard University.

Bruce Spiess began the day by thanking each person for attending: “Every healthcare professional in cardiac surgery is dedicated,” said Spiess. “And each is determined to provide the best possible care. That’s not in question. But despite our dedication and

determination, our human proclivity for error puts our patients at risk. To change this will require significant dedication and persistence over many years. It will require a cultural change. It will take the full engagement and enthusiasm of our representative societies. And the presence here of so many dedicated individuals indicates that this will be possible."

Those in attendance agreed. Here are just a few of their comments:

"The patient perspective is important and we need patients involved or in the planning."

"Frame the problems not as problems but as opportunities."

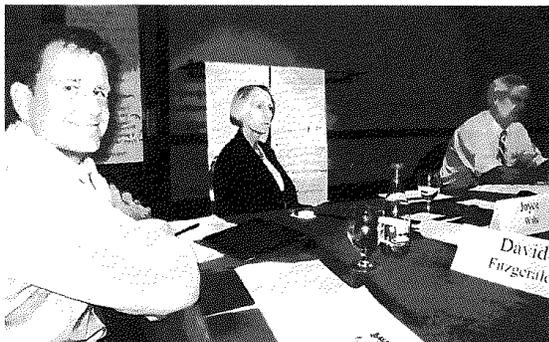
"Respect is a behavior and through repetitive behavior you can develop trust."

"How can we define and better share best practices?" —nurse

"Develop the metrics for safety in cardiac operating rooms and through that address business cases of how we will be successful."

"FOCUS could/should address a fundamental lack of knowledge about patient safety among our colleagues. We should develop a patient safety manual, encourage societies to endorse it as a must-read for members."

"It is hard to document the absence of something. It is easier to document when near misses happen."



"Even the best athletes in the world have coaches. Shouldn't we have them as well?" —surgeon

The following people gathered in Boston for a daylong Symposium facilitated by Christine Cole, Kennedy School of Business, Harvard University:

ATTENDEES

James Abernathy, MD, MPH, FASE, Anesthesiologist
Director, Cardiac Anesthesia, Medical University of South Carolina, Charleston, SC

Mary Frances Cedorchuck, Nurse Manager Cardiac Surgery
Beth Israel Deaconess Hospital, Boston, MA

Michael Culig, MD, FACS, Cardiac Surgeon
Forbes Regional Hospital, Monroeville, PA

Abe DeAnda Jr., MD, FACS, Cardiac Surgeon
Associate Professor, Cardiothoracic Surgery, NYU-Langone Medical Center, New York, NY

David Fitzgerald, CCP, Chair, AmSECT, Perfusionist
Inova Fairfax Hospital, Fairfax, VA

Chris Goeschel, ScD, MPA, MPS, RN
Armstrong Institute for Patient Safety, Johns Hopkins University, Baltimore, MD

Elizabeth Martinez, MD, MHS, Anesthesiologist
Mass General Hospital, Boston, MA

John Melleky, CFRE
SCAF staff, Richmond, VA

Nancy Nussmeier, MD, Anesthesiologist
Professor, Department of Anesthesiology, SUNY, Syracuse, NY

Bruce Searles, BS, CCP, Perfusionist
Dept. of Cardiovascular Perfusion, SUNY Upstate Medical University, Syracuse, NY

Scott Shappell, PhD, Human Factors Engineer
Professor, Clemson University, Clemson, SC

Stanton Keith Shernan, MD, Anesthesiologist
Brigham and Women's Hospital, Boston MA

Linda Shore-Lesserson, MD, Anesthesiologist
Secretary Treasurer SCA, Professor at Albert Einstein School of Medicine, Bronx, NY

Patricia Siefert, RN
Cardiovascular Operating Room, Inova Fairfax Hospital, Fairfax, VA

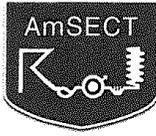
Bruce D. Spiess, MD, Chair, FOCUS Steering Committee
Professor of Anesthesiology, Senior Fellow VCURES, Virginia Commonwealth University, Richmond, VA

Thoralf Sundt, MD, Cardiac Surgeon
Chair, Thoracic Surgery, Mass. General Hospital, Boston, MA

Paul Uhlig, MD, MPA, FACS, Cardiac Surgeon
Central Plains Cardiothoracic Surgery, Wichita, KS

Joyce Wahr, MD, Anesthesiologist
Chair, SCA Foundation, University of Michigan, Ann Arbor, MI

Three others also attended: Jan Headley, Director, Edwards Life Sciences and Jill Wroblewski, Clinical Program Manager, Nonin Medical, both strong supporters of FOCUS.



AMERICAN SOCIETY OF
EXTRACORPOREAL TECHNOLOGY

Board of Health Professions
Virginia Department of Health Professions
9960 Mayland Drive, Suite #300
Henrico, VA 23233

On behalf of the American Society of Extracorporeal Technology (AmSECT), I am writing in support of professional licensure for clinical perfusionists in the State of Virginia.

The clinical perfusionist is an individual qualified by professional credentialing and academic and clinical education to provide a myriad of extracorporeal patient care services. Perfusionists apply these services through the use of complex medical devices and related technology, such as the "heart-lung machine", to provide cardiovascular surgeons the means to successfully complete many types of cardiac and pulmonary surgical procedures. The demand for excellence from a perfusionist during surgery is substantial and continuous, since patient care and safety are top priorities.

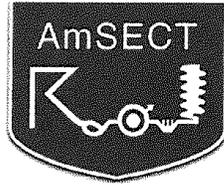
We believe it is necessary that perfusionists should be recognized as licensed professionals that are held to the same professional standards and accountability as physicians, nurses, physician assistants and respiratory therapists. The recognition being sought is not unique to other allied health care professionals in the State. Perfusionists are already licensed professionals in eighteen States.

As the national professional association for perfusion professionals, we believe that it will be in the best patient safety interests of the citizens of Virginia that perfusionists be required to graduate from a nationally accredited training program, pass a national certification examination, and attend appropriate continuing educational programs to ensure that safe patient care is delivered in hospital operating rooms, and other hospital settings, to be legally permitted to practice our profession in any healthcare facility in the State.

Sincerely,

David Fitzgerald, CCP
President

National Headquarters
2209 Dickens Road | Richmond, VA 23230-2005 | (804) 565-6363 | Fax (804) 282-0090
Email: amsect@amsect.org | www.AmSECT.org



AmSECT's Recommendation on Portable and Percutaneous Mechanical Circulatory Support Devices

The American Society of ExtraCorporeal Technology (AmSECT) is the world's largest professional society of cardiovascular perfusionists. AmSECT seeks to foster improved care, safety and outcomes for patients supported with extracorporeal devices. Perfusionists are the only medical professionals whose scope of practice expressly includes the utilization of extracorporeal devices to support patients in a variety of clinical circumstances. Perfusionists are qualified through CAAHEP-accredited educational programs and certified by the American Board of Cardiovascular Perfusion.

It is AmSECT's position that optimal patient care and safety must not be compromised. Mechanical Circulatory Support (MCS) devices which are a variation on, or are substantially equivalent to, current systems operated by perfusionists are beginning to be utilized by other health care providers. AmSECT has charged its Mechanical Circulatory Support Committee with providing knowledge, guidance and insight into MCS devices.

The MCS Committee continues to evaluate the available information regarding the current and pending generation of devices. Upon deliberation, the MCS Committee finds that safe and effective operation of these life-sustaining systems requires that a qualified perfusionist directly participate in or supervise their use. The introduction of such life support devices into the clinical setting without the involvement of a properly trained cardiovascular perfusionist will jeopardize safety and subject patients to substantial and unnecessary risk of injury. AmSECT strongly recommends that a perfusionist qualified by formal education and possessing clinical expertise be utilized directly or in a supervisory capacity throughout the implementation, operation and management of all MCS systems.

We welcome any questions and further discussion of our concerns and position on this matter.

Susan J. Englert
AmSECT President

David C. Fitzgerald
AmSECT President-Elect

Robert C. Groom
AmSECT Treasurer

William J. DeBois
AmSECT Secretary

Tim Reynolds
Zone 1 Director

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Zone 1 Director

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Zone 2 Director

Bryan Lich
Zone 3 Director

David Webb
Zone 3 Director

Nicholas B. Mellas
Zone 4 Director

James A. Reagor
Zone 4 Director

Board of Directors
American Society of ExtraCorporeal Technology
January 13, 2011



Virginia Perfusion Society
Inova Fairfax Hospital, Cardiovascular Perfusion
3300 Gallows Road, Falls Church, VA 22042



David Fitzgerald, CCP President
Richard Zacour, CCP Vice President
Mike Brown, CCP Board Member
Zack Beckman, CCP, Board Member

PERFUSIONIST STATE PRACTICE ACTS 2011

LICENSING

State	Statute Citation	Enacted Public Law	Year Enacted /Amended
Arkansas	Title 17, Subtitle 3, Chap 104	SB 499, PL 888	1999
Connecticut	Title 20, 381b Sec. 20-162	HB 5684	2005
Georgia	Chap 34 Title 43-34-170	HB 69	2002
Illinois	225 ILCS 125; 20 ILCS 2105/2105-15(7)	P.A. 91-580	2000
Louisiana	L.R.S. Ch 15, Title 37:1331 - 1344	SB 315, PL 811	2003
Maryland	Section 14-5E-01-26-5E-25	HB 287	2011
Massachusetts	Ch 112 MARS Sec 212-219	SB 2081	2000
Missouri	RSMO Ch 324 324.001-1148	SB 141, HB 567	1997
Nebraska	Title 19, R.S.Supp. 38-2701- 2712	LB 236	2001
New Jersey	N.J.S.A. 45:9-37,94	AB 2114	2007
Nevada	Chap 630 NRS Sec. 3, Sec. 4-14	SB 269,	1999
North Carolina	NCGS-Chap 90 Art 40 § 90-682	SB 1059	2009
Oklahoma	59 OS SEC 2051-2071; OAC 527:1-1-1.	SB 788	2005
Pennsylvania	63 P.S. § 422.1 et seq. 49 PA. CODE, Chap16, 17,18. and 63 P.S. §§ 271.1 - 271.18. 49 PA. CODE §§ 25.1-25.607	SB 500, 501	1996
Tennessee	Title 63 Chap 28 Sec101-118	SB 310	2002
Texas	TX Occ Code, Chapter 603	Acts 1993, 73,Leg. Chap 545	1994
Wisconsin	Chap (1) (d): 448.03 (1)(c), 448.04 (1)(d)	PL 89	1999

TITLING

State	Statute Citation	Enacted Public Law	Year Enacted
California	Business & Professions Code Chapter 5.67	AB 566	1992



Virginia Perfusion Society
Inova Fairfax Hospital, Cardiovascular Perfusion
3300 Gallows Road, Falls Church, VA 22042



David Fitzgerald, CCP President
 Richard Zacour, CCP Vice President
 Mike Brown, CCP Board Member
 Zack Beckman, CCP, Board Member

Disciplinary Actions Taken Against Licensed Perfusionists

Licensed Perfusionist States	Number of Disciplinary Actions
Arkansas	<i>Not Publicly Available</i>
California	0
Connecticut	0
Georgia	6
Illinois	4
Louisiana	3
Maryland <i>(Enacted in 2011)</i>	0
Massachusetts **	3
Missouri **	1
Nebraska	0
Nevada <i>(Regulations finalized 2010)</i>	0
New Jersey	3
North Carolina **	3
Oklahoma	4
Pennsylvania <i>(Regulations finalized 2011)</i>	0
Tennessee	4
Texas **	5
Wisconsin	2
Total	38

** State requires maintaining American Board of Cardiovascular Perfusion professional certification to renew a state license.

Disciplinary Actions include the following: Failure to renew a license on time; Practicing without a valid license; Failure to maintain ABCP certification and loss of license; Violation of federal HIPPA law; Complaint filed and upheld for unprofessional practice; Probationary suspension for substance abuse; License revocation for substance abuse.

Covers time period 1999 to 2010. Figures do not include ongoing complaint investigations.

An Introduction to the Profession and Issues Concerning the Practice and Regulation of Clinical Perfusion

*Prepared for Government Officials and Public Policy Makers
by the Government Relations Committee of AmSECT*

Since 1995 the Board of Directors of the American Society of ExtraCorporeal Technology (AmSECT) has recommended the legal credentialing of perfusionists through state-mandated licensure. The society has sustained an aggressive posture regarding the need for state regulation of perfusionists in a manner similar to other health care professionals who provide patient care in health care facilities in the United States. AmSECT has continued to fund a government relations committee to advocate, educate, and provide assistance to perfusionists in this country to gain this important legal credential.

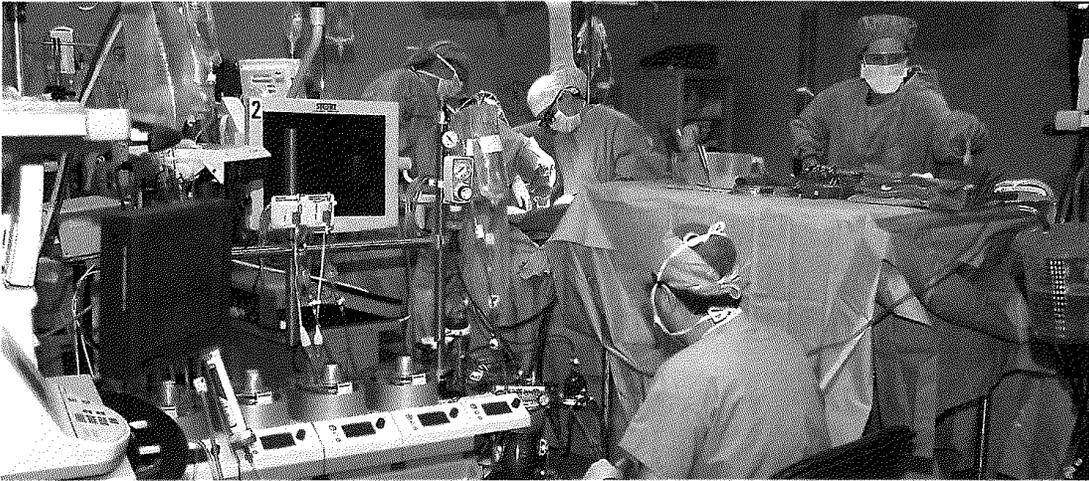
Clinical perfusionists are highly skilled professionals who operate extracorporeal circulation (meaning blood outside the body) equipment during any medical situation where it is necessary to safely support or replace a patient's cardiopulmonary or circulatory functions. They use a varied and complex array of equipment that demands diligent training and comprehension of a wide variety of medical science and related technologies. Perfusionists must possess a high level of cognitive ability and professional judgment during critical surgical procedures.

Clinical perfusionists provide critical care services to cardiac, vascular, and other patients in hospitals. They receive their education and training in formal university programs structured for this unique profession. It includes both didactic and clinical experience fundamental to the sophistication, demands, and success of modern cardiac surgery. This education comprises anatomy, physiology, pharmacology, pathology; subjects which are taught in medical schools. Perfusionists frequently administer medications, blood products, and anesthetic agents during surgery while working in collaboration with their physician colleagues. Education and research are a fundamental part of the clinical perfusionist's scope of practice. Like surgeons, anesthesiologists, nurses, and physician assistants, perfusionists are an indispensable professional member of the cardiovascular team.

The compulsory regulation of perfusionists through state licensure would serve the greater public interest for the hundreds of thousands of patients who receive the care of a perfusionist each year. This public oversight will ensure that only properly educated professionals are permitted to work in this specialty. It will set minimum levels of medical provider qualifications by mandated academic, examination, and continuing education standards unique to the profession. The health care needs of the citizens of the United States would benefit by ensuring perfusionists meet expectations required of virtually every other health care professional.

By 2010, half of the clinical perfusionists providing direct patient care in this country worked under professional practice acts defined by legislation in 17 states. ***In all other states without this regulation there exist no legal and enforceable standards regulating the licensing of a person who works as a perfusionist and provides medical care to a patient.*** In many other states perfusionists are presently engaged at various levels in campaigns to establish legislation that will regulate this profession and increase the number of states that have proactively set minimum standards for these important professionals.

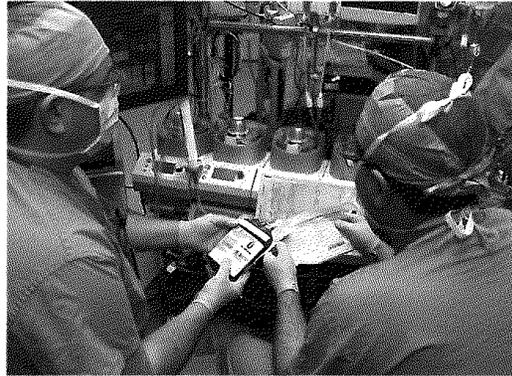
The Scope of Practice of Clinical Perfusion



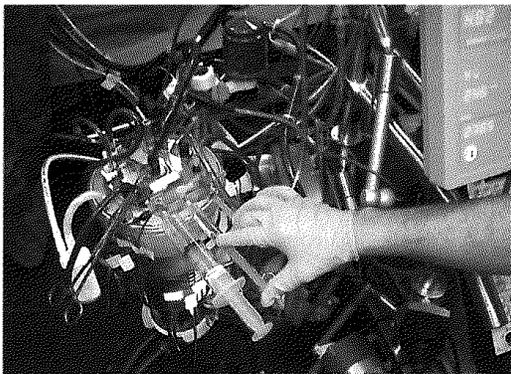
The cardiovascular surgical team and perfusionist at the heart-lung machine

Extracorporeal Support

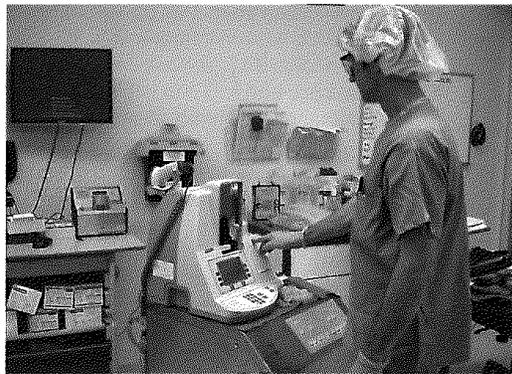
- Cardiopulmonary bypass for adult, pediatric, and neonatal patients
- Cardiopulmonary bypass for congenital and acquired cardiovascular disorders
- Extracorporeal circulatory support for renal, neurological, hepatic and vascular surgery
- Extracorporeal circulation for long term support of failing respiratory and/or cardiac function
- Extracorporeal resuscitation



Checking blood for transfusion

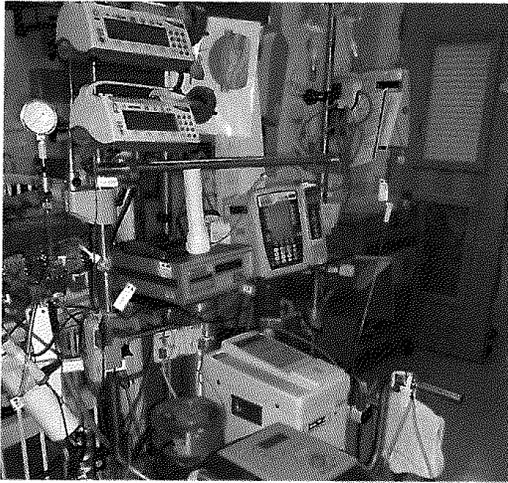


Administering medications to the extracorporeal circuit

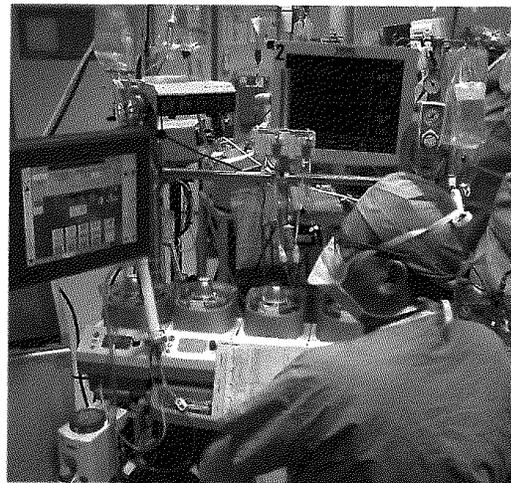


Analyzing blood coagulation parameters

The Scope of Practice of Clinical Perfusion



Extracorporeal Membrane Oxygenation (ECMO) in the ICU



Monitoring patient physiology and heart-lung machine functions

Blood Management

- Autotransfusion
- Platelet gel production
- Non-differentiated progenitor cell harvest
- Acute normovolemic hemodilution
- Hemostasis monitoring and analysis
- Phlebotomy

Heart Failure Therapy and Support

- Ventricular assist device management
- Intra-aortic balloon counterpulsation
- Temporary pacemaker management
- External counterpulsation
- Transportation of extracorporeal supported patients
- Hemofiltration (i.e. "aquapheresis")
- Periodic flow augmentation therapy



Extracorporeal Membrane Oxygenation (ECMO) support



Operating the cell washer blood salvaging machine

3

The Scope of Practice of Clinical Perfusion

Associated Extracorporeal Support Functions

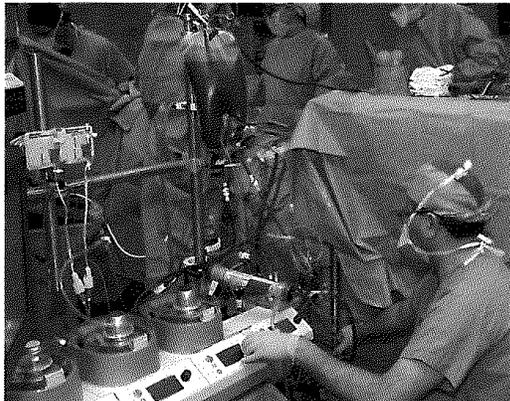
- Myocardial protection
- Hemofiltration/hemodialysis
- Thermal regulation
- Anticoagulation and hemostasis monitoring, analysis, and intervention
- Blood gas and blood chemistry monitoring, analysis, and intervention
- Physiological monitoring, analysis, and intervention
- Administration of blood components, pharmaceuticals, and anesthetic agents



Performing a platelet concentration procedure

Other Clinical Responsibilities

- Isolated limb/organ perfusion
- Isolated limb/organ delivery of chemotherapeutics, progenitor cells, gene therapy vectors, etc.
- Organ procurement
- Thermogenic lavage
- Organ preservation
- Dialysis
- Surgical assistance
- Electrophysiological analysis
- Therapeutic hyperthermia
- Therapeutic hypothermia
- Intravascular membrane oxygenation



Performing a blood concentration procedure

Non-Clinical Responsibilities

- Documentation of duties via the official medical record
- Education, including the establishment and management of educational programs for new and current clinical perfusionists, other healthcare providers, and consumers
- Administration, including the management of all aspects (technical, fiscal, workflow, and human resources) of clinical perfusion operations
- Quality control and assurance
- Regulatory compliance
- Competency/performance evaluation

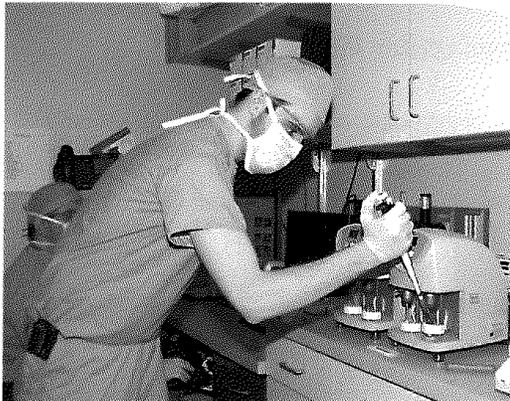


Performing blood gas analysis

The Scope of Practice of Clinical Perfusion



Operating the intra-aortic balloon pump



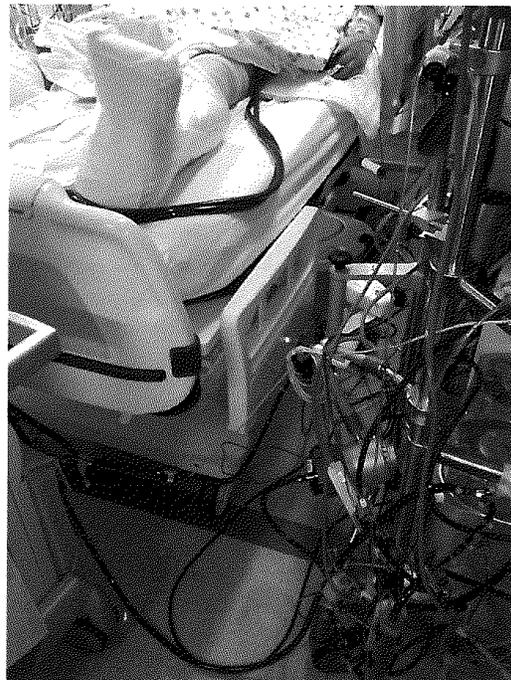
Performing thrombelastography on blood



Testing blood coagulation and platelet function

Professional Performance

- Obtains and maintains appropriate professional credentials
- Works in partnership with other health care professionals to provide the best medical care possible for all patients
- Adheres to the standards, policies, and procedures adopted by the profession and regulated by law
- Stays current with required continuing medical education (CME) in order to stay abreast of changes in the field of extracorporeal technology and to maintain professional credentials
- Participates in continuing education activities through professional organizations, to enhance knowledge, skills and performance
- Adheres to the accepted professional ethical standards as defined by the Code of Ethics
- Acts as a patient advocate supporting patient rights
- Designs, coordinates, and implements original investigation
- Critically evaluates published research



Extracorporeal Membrane Oxygenation (ECMO) support

YOUR SOURCES FOR MORE INFORMATION ABOUT THIS VITAL PROFESSION

American Society of ExtraCorporeal Technology

AmSECT

The mission of AmSECT is to foster improved patient care and safety by providing for the continuing education and professional needs of the extracorporeal circulation technology community. The society was founded in 1964. In 1976, with the active support of the American Association for Thoracic Surgery (AATS) and the Society of Thoracic Surgeons (STS), AmSECT was successful in receiving occupational recognition by the American Medical Association (AMA). AmSECT fosters the scientific dissemination of knowledge through the publication of information in the indexed *Journal of ExtraCorporeal Technology*. The society represents the professional clinical practice concerns of perfusionists to state and federal authorities. AmSECT currently represents nearly 2000 perfusionists in all fifty states, and to this day remains the largest professional society devoted to the clinical perfusionist profession.

Additional information can be found at www.amsect.org.

American Board of Cardiovascular Perfusion

ABCP

The ABCP was established in 1975. The primary purpose of the Board, and therefore its most essential function, is protection of the public through the establishment and maintenance of standards in the field of cardiovascular perfusion. To achieve this objective, the Board has established qualifications for examination and procedures for recertification. Certification in cardiovascular perfusion (CCP-Certified Clinical Perfusionist) is evidence that a perfusionist's qualifications for operation of extracorporeal equipment are recognized by his/her peers.

Additional information can be found at: www.abcp.org.

Extracorporeal Life Support Organization

ELSO

ELSO, founded in 1989, is an international consortium of health care professionals including perfusionists and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Crucial is the promotion of a broad multidisciplinary collaboration. The primary mission of the organization is to maintain a registry of, at least, the use of extracorporeal membrane oxygenation (ECMO) in active ELSO centers. As appropriate, registries of other novel forms of organ system support are within the purview of ELSO.

Registry data is to be used to support clinical research, support regulatory agencies, and support individual ELSO centers. ELSO provides educational programs for active centers as well as for the broader medical and lay communities. Perfusionists have been and remain intimately involved in ELSO and the procedures the organization maintains in its registry. A representative from the perfusion community retains a liaison status on the ELSO Steering Committee and participates and attends leadership emails and meetings, respectively. In addition, ELSO often utilizes perfusionists to present at their international meetings as well as author chapters relative to product development and utilization.

Additional information can be found at: www.else.med.umich.edu.

YOUR SOURCES FOR MORE INFORMATION ABOUT THIS VITAL PROFESSION

Commission on Accreditation of Allied Health Education Programs

CAAHEP

CAAHEP is the largest national programmatic accrediting body in the health sciences field. In collaboration with its Committees on Accreditation, CAAHEP reviews and accredits over 2000 educational programs in twenty health science occupations. CAAHEP is recognized by the Council for Higher Education Accreditation (CHEA).

Additional information can be found at www.caahep.org and www.chea.org.

Accreditation Committee for Perfusion Education

AC-PE

The AC-PE is a Joint Review Committee of the Commission on Accreditation of Allied Health Education Programs (CAAHEP) for Perfusion Education. The AC-PE is jointly sponsored by:

- American Society of ExtraCorporeal Technology
- American Association for Thoracic Surgery
- Society of Thoracic Surgeons
- American Board of Cardiovascular Perfusion
- American Academy of Cardiovascular Perfusion
- Perfusion Program Director's Council
- Society of Cardiovascular Anesthesiologists

The AC-PE and its sponsoring organizations are members of CAAHEP. The major role played by the AC-PE is protection of the perfusion student. The AC-PE reviews perfusion programs through annual reports and by sending perfusionists on site visit teams to perfusion schools for on-site visits, makes assessments of the schools' educational content, and then makes its recommendations to CAAHEP. Additional information can be found at: www.ac-pe.org.

Perfusion Program Director's Council

PPDC

The PPDC was established in 1995 to provide a forum for the exchange of information on scientific/educational issues among program directors to enhance the educational process in perfusion technology. It also provides representation to and becomes a vehicle for the receipt of information from organizational and professional societies that have input into the perfusion profession, its education, and accreditation. It further provides a unified voice of expression for perfusion education program directors.

Additional information can be found at: www.perf-ed.org.

International Board of Blood Management

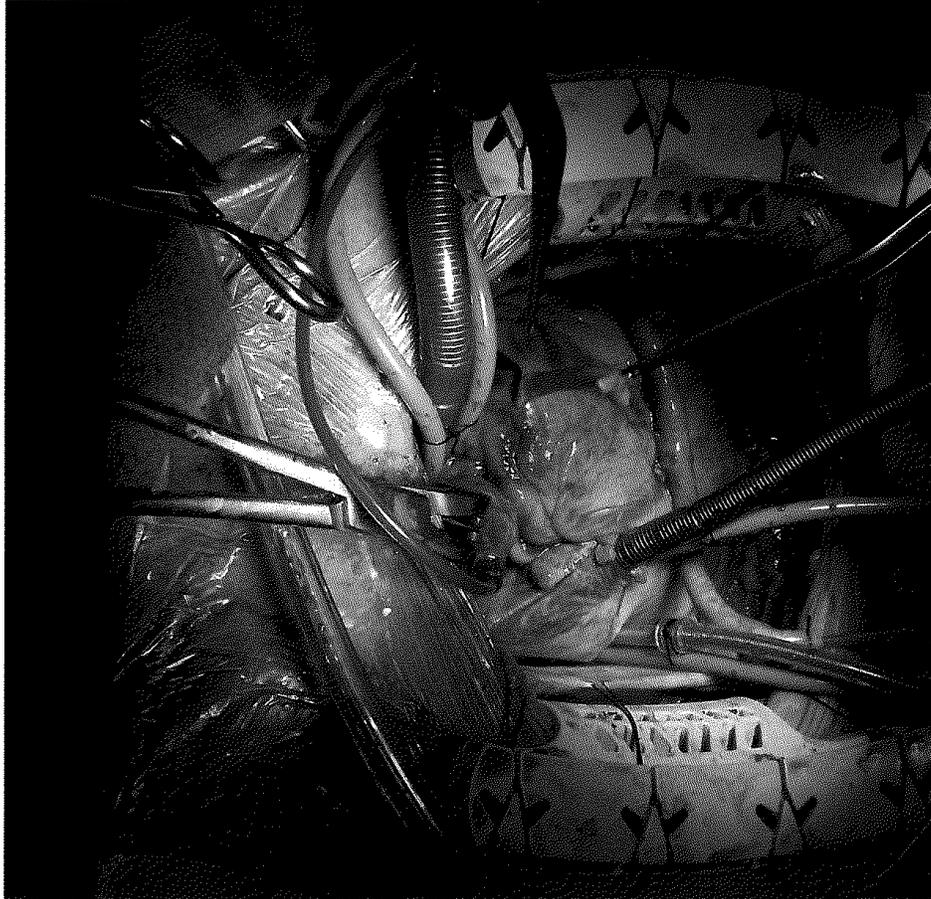
IBBM

The IBBM promotes education and sound scientific principles to advance the safe and competent practice of perioperative blood management. It offers a formal certification examination process for clinicians who practice perioperative blood management techniques. The IBBM was created with guidance from AmSECT and the American Association of Blood Banks (AABB).

Additional information can be found at: www.intbbm.org.

American Society of ExtraCorporeal Technology

Clinical Perfusionists are highly skilled professionals who operate extracorporeal (meaning blood outside the body) circulation equipment during any medical situation where it is necessary to safely support or replace a patient's cardiopulmonary or circulatory functions.



The heart cannulated for extracorporeal support

In most states, there are no legal and enforceable standards regulating the licensing of a person who works as a perfusionist and provides medical care to a patient.

www.amsect.org

**VIRGINIA BOARD OF HEALTH PROFESSIONS
VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS**

STUDY WORKPLAN DRAFT

**Review of Potential Pharmacist and Pharmacy Technician Scope of Practice Barriers to the
Development of Effective Team Approaches to Healthcare Delivery in Virginia**

May 8, 2012

Background and Authority

At the February 15, 2011 meeting of the Virginia Board of Health Professions, the Secretary of Health and Human Resources requested the Board's assistance in addressing Virginia's health reform issues. The Secretary's request followed the publication in December 2010 of the Virginia Health Reform Initiative Advisory Council's (VHRI) latest findings and recommendations.

Led by Secretary Hazel and commissioned in August of 2010 by Governor Robert F. McDonnell, VHRI's charge is to develop recommendations for implementing health reform in Virginia and to search for innovative solutions to meet Virginia's needs in 2011 and beyond. To date, six VHRI task forces have been formed to address the following key interrelated issues: Medicaid Reform, Service Delivery and Payment Reform, Technology, Insurance Reform, Purchaser Perspectives, and, of greatest relevance to the Department and Board, Capacity.

The Capacity Task Force noted in the December VHRI report that health workforce capacity must be increased to ensure all Virginian's have access to affordable and high quality care. Even now before increased coverage from federal health reform takes effect, there are many medical, dental, and mental health underserved areas throughout across the state. And, looming shortages are predicted for most health service providers due to increases in Virginia's population size and age, alone. With increase coverage slated to go into effect in 2014, the gap between supply and demand can be expected to only worsen without help.

The Capacity Task Force viewed that effective capacity could be reached with increases in health professional supply, expanded use of technology to reach underserved areas, optimizing efforts to re-organize health care delivery through teams that effectively deploy non-physicians, and permitting health professionals to practice up to the evidence-based limits of their education and training in ways not currently possible with existing scope of practice and supervisory restrictions. To inform these approaches, the Task Force further recommended multi-dimensional studies which include reviews of promising team practice approaches and examination of how current scope of practice limits may needlessly restrict Virginia's ability to take full advantage of best practice team models of care delivery.

The Board of Health Professions is authorized by the General Assembly with a variety of powers and duties specified in §§54.1-2500, 54.1-2409.2, 54.1- 2410 *et seq.*, 54.1-2729 and 54.1-2730 *et seq.* of the *Code of Virginia*. Of greatest relevance here is §54.1-2510 (1), (7), and (12) enable the Board to evaluate the need for coordination among health regulatory boards, to advise on matters relating to the regulation or deregulation of health care professions and occupations, and

to examine scope of practice conflicts involving professions and advise on the nature and degree of such conflicts.

Thus, the Board determined at its May 3, 2010 meeting that it can most effectively assist VHRI and the Capacity Task Force by objectively examining the aforementioned current scope of practice limits in light of the latest evidence-based policy research and available data related to safety and effectiveness. With the assistance of member Boards and invited input from experts and public and private stakeholders, this review will aim to identify barriers to safe healthcare access and effective team practice that may exist due to current scope of practice limits and will determine the changes, if any, that should be made to scope of practice and regulatory policies to best enable effective team approaches for the care of Virginia's patients. The goal is not to replace physicians with non-physicians but to lessen unnecessary restrictions to ease the burden on practitioners and better ensure access to healthcare through strengthened health professional teams.

The Board referred the project to the Regulatory Research Committee and directed that the first review address scope of practice issues in Virginia relating to Nurse Practitioners and this second study to focus on Pharmacists and Pharmacy Technicians. All reviews are to consider scope of practice issues in the perspective of their potential role in team health care delivery models that have evidence of effectiveness in helping to address workforce shortage. Subsequent to this review, the Committee will determine future professions to be highlighted based upon the evolving evidence related to effective team models and the workforce research findings for professions under review by the DHP Healthcare Workforce Data Center and Virginia Health Workforce Development Authority.

Methods

Throughout the review, it is understood that the Board will strive to work in concert with the efforts of its member Boards, the VHRI Capacity Task Force, the Department's Healthcare Workforce Data Center, the Health Care Workforce Development Authority, and others working to assist the Secretary in these matters.

In keeping with constitutional principles, Virginia statutes, and nationally recognized research standards, the Board has developed a standard methodology to address key issues of relevance in gauging the need for regulation of individual health professions. The specifics are fully described in the Board's *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions*, available from the Board's website: http://www.dhp.virginia.gov/bhp/bhp_guidelines.htm) under Guidance Document 75-2 [Appropriate Criteria in Determining the Need for Regulation of Any Health Care Occupation or Professions, revised February 1998](#). (Hereinafter this is referred to as "the Policies and Procedures"). The Policies and Procedures will be employed in this study and modified as deemed appropriate by the Committee. It is understood that the Policies and Procedures' seven evaluative criteria apply most directly to determining *whether* a profession should be regulated and to what degree. But, they also provide a standard conceptual framework with proscribed questions and research methods that have been employed for over two decades to successfully address key policy issues related to health professional regulation. The seven Criteria typically used in sunrise review studies are as follows:

- 1. Risk of Harm to the Consumer**
- 2. Specialized Skills and Training**
- 3. Autonomous Practice**

4. **Scope of Practice**
5. **Economic Costs**
6. **Alternatives to Regulation**
7. **Least Restrictive Regulation**

Since Pharmacists and Pharmacy Technicians are already licensed, the first five Criteria will chiefly guide the study. This study will provide background information on the qualifications and scopes of practice of Pharmacists and Pharmacy Technicians in Virginia and elsewhere and on major existing and described emerging health delivery models.

The following provide the chief questions recommended to be addressed:

Background

1. What are the current qualifications that Virginia's Pharmacists and Pharmacy Technicians must demonstrate to become licensed? Do they differ from other states?
 - a. What are the educational or training requirements for entry into each profession? (sample curricula) Which programs are acceptable? How are these programs accredited? By whom?
 - b. What are the minimal competencies (knowledge, skills, and abilities) required for entry into the profession? As determined by whom?
 - c. Which examinations are used to assess entry-level competency?
 - i. Who develops and administers the examination?
 - ii. What content domains are tested?
 - iii. Are the examinations psychometrically sound – in keeping with *The Standards for Educational and Psychological Testing*?
2. How do Pharmacists and Pharmacy Technicians maintain continuing competency? Does it differ in other states?
3. What is the Scope of Practice in Virginia for Pharmacists? For Pharmacy Technicians? How does it differ from other states?
4. Describe existing team delivery models of care that utilize Pharmacists and Pharmacy Technicians in Virginia and elsewhere.
5. Based upon the emerging literature, describe existing and anticipated team delivery models that may evolve as a result of the federal health reform and the potential role(s) for Pharmacists and Pharmacy Technicians in those models.

Risk of Harm to the Consumer

1. What are the typical functions performed and services provided by Pharmacists and Pharmacy Technicians in Virginia and elsewhere?
2. Is there evidence of harm from either Pharmacists or Pharmacy Technicians with expanded scopes of practice relative to that in Virginia? If any,
 - a. To what can it be attributed (lack of knowledge, skills, characteristics of the patients, etc)?
 - b. How is the evidence documented (Board discipline, malpractice cases, criminal cases, other administrative disciplinary actions)?

- c. Characterize the type of harm (physical, emotional, mental, social, or financial)
 - d. How does this compare with other, similar health professions, generally?
3. Does a potential for fraud exist because of the inability of the public to make informed choice in selecting a competent practitioner?
 4. Does a potential for fraud exist because of the inability for third party payors to determine competency?
 5. Is the public seeking greater accountability of this group?

Specialized Skills and Training

NOTE: The following are in addition to the qualification-related questions previously posed for the “Background” section of the evaluation.

1. Are there currently recognized or emerging specialties/levels within this profession?
 - a. If so what are they? How are they recognized? By whom and through what mechanism?
 - b. Are they categorized according to function? Services performed? Characteristics of clients/patients? Combination? Other?
 - c. How can the public differentiate among these specialties or levels?

Autonomous Practice

1. What is the nature of the judgments and decisions that Pharmacists and Pharmacy Technicians currently entitled to make in practice in Virginia? Does this differ in states with more expanded scope of practice? If so, how?
2. Which functions typically performed by Pharmacists and, separately, Pharmacy Technicians in Virginia are **unsupervised** (i.e., neither directly monitored nor routinely checked)?
 - a. What proportion of the practitioner’s time is spent in unsupervised activity?
 - b. Who is legally accountable or civilly liable for acts performed with no supervision?
3. Which functions are performed **only under supervision** in Virginia?
 - a. Is the supervision *direct* (i.e., the supervisor is on the premises and responsible) or *general* (i.e., the supervisor is responsible but not necessarily on the premises)?
 - b. How frequently is supervision provided? Where? And for what purpose?
 - c. Who is legally accountable or civilly liable for acts performed under supervision?
4. Describe the nature of supervision.
5. Describe the typical work settings, including supervisory arrangements and interactions of the practitioner with other regulated and unregulated occupations and professions.
6. Are patients/clients **referred to** these professions for care or other services? By whom? Describe a typical referral mechanism.
7. Are patients/clients **referred from** these professions to other practitioners? Describe a typical referral mechanism. How and on what basis are decisions made to refer?

Scope of Practice

1. Which existing functions of this profession in Virginia are **similar to** those performed by other professions? Which profession(s)?
2. What additional functions, if any, are performed by these professions in other states?
3. Which functions of this profession are **distinct from** other similar health professions in Virginia? Which profession(s)? In other states?

Economic Costs

1. What are the range and average incomes of members of each of these professions in the Commonwealth? In adjoining states? Nationally?
2. If the data are available, what are the typical fees for service provided by these professions in Virginia? In adjoining states? Nationally?
3. Is there evidence that expanding the scope of practice would
 - a. Increase the cost for services?
 - b. Increase salaries for those employed by health delivery organizations?
 - c. Restrict other professions in providing care?
 - d. Other deleterious economic effects?
4. Address issues related to supply and demand and distribution of resources including discussion of insurance reimbursement.

The following steps are recommended for this review

1. Conduct a comprehensive review of the pertinent policy and professional literature.
2. Review and summarize available relevant empirical data as may be available from pertinent research studies, malpractice insurance carriers, and other sources.
3. Review relevant federal and state laws, regulations and governmental policies.
4. Review other states' relevant experiences with scope and practice expansion and team approaches to care delivery.
5. Develop a report of research findings, to date, and solicit public comment on reports and other insights through hearing and written comment period.
6. Publish second draft of the report with summary of public comments.
7. Develop final report with recommendations, including proposed legislative language as deemed appropriate by the Committee..
8. Present final report and recommendations to the full Board for review and approval.
9. Forward to the Director for review and comment.
10. Upon approval from the Director forward to the Secretary for final review and comment.

11. Prepare the final report for publication and electronic posting and dissemination to interested parties.

Timetable and Resources

This study will be conducted with existing staff and within the budget for the remainder of FY2012 and half of FY2013.

The following timeline is submitted for the Committee's consideration:

May 8, 2012	Committee Review of Workplan and Progress to Date
July 13, 2012	1st Draft Report to Committee Members & Posted to the Website
July 23, 2012	Public Hearing/Committee Meeting
August 17, 2012	2 nd Draft Report to Committee Members & Posted to the Website
September 17, 2012	Committee Meeting/Recommendations
October 2, 2012	Committee Report to the Full Board/Final Recommendations